

1

3,315,802

## PACKAGE FOR STERILE STORAGE OF SURGICAL DEVICES AND ACCESSORIES

Hans Christian Rønnow Lønholdt, Espergaerde, and Knud Maro Henrik Bjarnø, Stenlose, Denmark, assignors to Novo Terapeutisk Laboratorium A/S, Copenhagen, Denmark, a Danish joint-stock company

Filed Oct. 22, 1965, Ser. No. 501,752

Claims priority, application Denmark, June 21, 1963, 2,966/63

15 Claims. (Cl. 206—56)

This application is a continuation-in-part of application Ser. No. 376,116, filed June 18, 1964, and now abandoned.

In surgery use is as known being made of a series of different devices, accessories and auxiliaries. The demand on sterility of such devices, accessories and auxiliaries is still increasing. Among said devices, accessories and auxiliaries may e.g. be mentioned suture and ligature materials, haemostatic forceps, wound retractors and wound clips, knives, scissors, forceps and catheters.

As far as a series of the said devices and auxiliaries are concerned, sterilization takes place in the hospitals, preferably by autoclaving, in that the devices or auxiliaries having been wrapped separately or several together are put into a tray or bowl which is placed into an autoclave and is autoclaved. This applies e.g. to peans, wound retractors and wound clips and to knives and scissors. The sterilized articles are then removed the very moment when they are to be used or they are put in unwrapped condition on the operating table in such case where they are to be at disposal with a very short notice.

Other devices, such as suture and ligature materials with appertaining needles, if any, are sterilized on an industrial basis outside the hospitals. Thus, they are presented in sterile sealed packages which are to be opened before use.

The present invention relates to a package for sterile storage of suture and ligature materials, peans, wound retractors, knives, catheters and other surgical devices and auxiliaries, and the object of the invention is to provide a package which on one hand reduces the danger of infection due to contamination of the sterile surgical devices and auxiliaries prior to their use, and on the other hand renders possible an easy and quick removal of the devices and auxiliaries from the packages.

The package according to the invention is of the kind which consists in or contains a bag destined for taking up the surgical articles, and it is characterized by the fact that the side-walls of said bag are slitted up from the open end of the bag so as to form flaps, said flaps being loaded with such weight that when the bag is placed bottom down the flaps will fall out to the sides and thereby provide free and easy admission to the interior of the bag.

The loading of the side-wall flaps is preferably effected by means of weighty strips provided at the free ends of the flaps.

When the package according to the invention consists only of the said bag referred to in the following as the flap bag, the package is to be used in such cases where the surgical devices are sterilized in the hospitals. The said devices are placed separately or several together in a flap bag of suitable size and the bags are placed in a bowl or a tray and are sterilized by autoclaving. When the said device or devices is or are to be used one grasps the bottom of the flap bag, the bottom is turned downwards, and the flaps will fall out to the sides, which provides an easy and free admission to the contents of the bag. In this manner a real unwrapping of the sterile device immediately prior to use is avoided, and the danger

2

of the device being made unsterile is reduced since it does not come into contact with the surrounding air before it is to be used, and not at all with the outer faces of the flap bag which might have become unsterile.

For storage of suture and ligature materials and other devices which are to be used only on one occasion and the final sterilization of which is made on an industrial scale upon finished packages, the flap bag is according to the invention placed in a sealed outer bag of germ-tight material having its bottom adjacent the extremity of the outer bag destined to be opened. Thus, when the outer bag is opened by cutting or tearing, with the opening turned upwards, the bottom of the flap bag will be apparent, and when grasping the bottom, pulling out the flap bag and turning the bag 180°, the flaps will automatically fall out to the sides and the contents of the bag will become easily and freely accessible for direct use. In this manner the contents of the flap bag will not come into contact with the outer faces of the flap bag having touched the edges of the outer bag, which edges might be unsterile, and it becomes unnecessary to carry out an additional tearing or cutting in order to get access to the sterile surgical device in the inner bag, such as has previously been the case.

In connection with surgical accessories having a considerable length it may also be appropriate to make use of an outer germ-tight bag, which may then surround only the open end of the flap bag.

In the production of the flap bag it is appropriate to make use of transparent foils of plastics which can be welded together by heating, e.g. by high-frequency welding. As examples of suitable plastics may be mentioned ethylcellulose, cellulose acetate, cellulose propionate, cellulose acetate butyrate, polyamides, such as polyamino undecanoic acid, polyvinyl compounds, polyesters, polyethylene, polypropylene, polymonochlorotrifluoroethylene and polytetrafluoroethylene. Use may also be made of laminates of two or more of the said plastics. Further papers, such as parchment paper, are also applicable.

If the flap bag is used together with a sealed outer bag of germ-tight material, the latter may also be produced from the same material as the flap bag. If the package according to the invention is used for sterile storage of suture or ligature material requiring a conditioning during the storing period by the presence in the package of a water-containing moistening agent being or the vapors of which being in contact with the suture or ligature material, the sealed outer bag should be prepared from a material being impermeable or difficultly permeable to the vapors of the employed moistening agent. Suitable materials for the said purpose are foils produced from appropriate laminates of the above mentioned plastics or foils of nylon, polymonochlorotrifluoroethylene, polytetrafluoroethylene or polyethylene glycolterephthalates. The sealed outer bag may also be produced from a laminated metallic foil, e.g. an aluminum foil being coated at its inner face with a thin film of polyethylene or another plastic which may be welded by the action of heat, and at its outer face with a thin layer of paper.

When selecting the material for the package according to the invention regard should be taken not only to the manner in which sterilization has been performed, but also to the purpose for which the package is intended. Some plastics, such as polyethylene, are not suitable when the sterilization takes place by autoclaving. When the package according to the invention is used for sterile storage of suture and ligature materials in the presence of a water-containing moistening agent, it is of course necessary that the employed materials be unable to be affected by the moistening agent and that the outer bag be impermeable thereto. The flap bag may be produced from a material being permeable to the moistening agent